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| 10/538,062 | 04/10/2006 | Ulrich Bockelmann | 273506US2PCT | 8893 |
| 22850 | 7590 | 02/22/2010 | | |
| OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P. 1940 DUKE STREET ALEXANDRIA, VA 22314 | | | EXAMINER LIN, JERRY | |
| | | | ART UNIT 1631 | PAPER NUMBER |
| | | | NOTIFICATION DATE 02/22/2010 | DELIVERY MODE ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/538,062 | Applicant(s) BOCKELMANN ET AL. | |
| | Examiner JERRY LIN | Art Unit 1631 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 5 and 6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 7-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>6/9/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election with traverse of Species A and DNA in Species D in the reply filed on November 30, 2009 is acknowledged. The traversal is on the ground(s) that there was no showing of a serious burden. This is not found persuasive because the examiner demonstrated that the different species lacked unity under PCT Rule 13.1. An inquiry into whether there was a serious burden on examination is irrelevant when demonstrated a lack of unity between species.

The requirement is still deemed proper and is therefore made FINAL.

Claims 5 and 6 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement.

Status of the Claims

Claims 1-4 and 7-19 are under examination. (claims 16 and 17 will be examined as they relate to DNA)

Claims 5 and 6 are withdrawn.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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3. Claims 1-4 and 7-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 1-4 and 7-19 are indefinite in claim 1, which recites each of the following:

I. The limitations “transistors (T1, T2, etc.)” and “region (5), a drain region (D)” in line 4, “zone (3)” in line 5, “zones (3)” in lines 7. It is unclear if the various recitations within the parenthesis are limitations of the claim.

Furthermore, for the term “transistors (T1,T2, etc.)” the metes and bounds of the term are unclear due to the recitation of “etc.” Additional, the term “zones (3)” is found in claim 3.

II. The limitation “the drain current/source-gate voltage/source-drain voltage” in lines 12 and 13 of claim 1. It is unclear whether current or voltage that is being measured. It is also unclear which of the source, gate, and/or drain has the current or voltage measured. In addition, the recitation “the drain current/source-gate voltage/source-drain voltage” lacks antecedent basis because a “drain current/source-gate voltage/source-drain voltage” is not previously recited. It is suggested that the word “the” be changed to “a.”

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-4, 7, 8, 14-16, and 18 are rejected under 35 U.S.C. 102(3) as being anticipated by Lindsay et al (U.S. Application Publication No. US 2004/0238379 A1, filed 7 August 2002).

Regarding claims 1-4, 15, 16, and 18, Lindsay et al teach a method for detecting at least one parameter representative of molecule probes fixed to active zones of a sensor in the form of a genechip comprising a plurality (i.e., network) of field effect transistors (paragraph 0040), wherein each field effect transistor (i.e., FET) has a source region, gate region, and a drain region (paragraph 0028), which forms an active zone on which the parameter is detected. Lindsay et al further teach bringing some of said active zones into contact with molecular probes in order to fix said probes; namely, DNA, which is a molecular probe, is injected into a genechip having a plurality of FETs each having a difference nucleic acid sequence thereon (paragraph 0040). The DNA is in a buffer with salts (paragraphs 0037 and 0032). Because the buffer solution is injected into the genechip having the plurality of FETs (paragraph 0040 and 0037), the active zones are bathed in the buffer. Lindsay et al also teach measuring at least one point of a drain current characteristic to detect (i.e., deduce) the representative parameter by comparison between at least two measurements obtained for probe molecules having been subjected to two different interactions (i.e. different target

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sequences) where the interactions are of the same type (i.e. hybridization) (paragraph 0033-0040), wherein a plurality of FETS (i.e., at least two) including a control FET are measured and compared (paragraph 0040).

Regarding claims 7 and 8, Lindsay et al also teach said measuring comprises applying a voltage between the drain region and source region (paragraph 0010) and the application of a drain current (paragraph 0018 and Figure 7).

Regarding claim 14, Lindsay et al further teach rinsing with an electrolyte solution (i.e., comprising a non-hybridizing target) before adding a solution containing target molecules, then taking a measurement (paragraphs 0036-0039),

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lindsay et al (U.S. Application Publication No. US 2004/0238379 A1, filed 7 August 2002) as applied to claims 1-4, 7, 8, 14-16, and 18 above, and further in view of Price (U.S. Patent No. 5,805,014, issued 8 September 1998).

Lindsay is applied as above.

While Lindsay et al teach the FETs that are depleted (paragraph 0027) and n-channel type (paragraph 0021), Lindsay et al. does not explicitly teach depleted n-channel type FETs with a negative gate bias.

However, Price teaches FETs in the form of depleted n-channel MOSFETs having a negative gate bias, which has the added advantage of providing a circuit that maintains the efficiency of a power supply by drawing minimal power (column 1, lines 55-67). Thus, Price teaches the known technique of using depleted n-channel MOSFETs having a negative gate bias.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the method comprising depleted and n-channel type FETs as taught by Lindsay et al so that the FETs are the depleted n-channel type FETs with a negative gate bias as taught by Price to arrive at the instantly claimed method with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would

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have resulted in a method having the added advantage of providing a circuit that maintains the efficiency of a power supply by drawing minimal power as explicitly taught by Price (column 1, lines 55-67). In addition, it would have been obvious to the ordinary artisan that the known technique of using the depleted n-channel type FETs with a negative gate bias of Price could have been applied to the method of Lindsay et al with predictable results because the known technique of using depleted n-channel type FETs with a negative gate bias of Price predictably results in FETs that are functionally equivalent to the FETs of Lindsay et al.

8. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lindsay et al (U.S. Application Publication No. US 2004/0238379 A1, filed 7 August 2002) as applied to claims 1-4, 15, 16, and 18 above, and further in view of Anderson et al (U.S. Patent No. 5,922,591, issued 13 July 1999).

Lindsay et al. is applied as above.

While Lindsay et al teach a buffer solution is injected into a genechip having a plurality of FETS each having a difference nucleic acid sequence thereon (paragraph 0040), Lindsay et al, does not teach a solution is circulated through the microfluidic channel to bring the solution into contact with at least one of the FETs.

However, Anderson et al teach a method comprising using a microfluidic device having an array of fixed probes in a chamber therein having a microfluidic channel (column 2, lines 20-45), wherein fluids are recirculated through the chamber, which has the added advantage of aiding in the mixing of samples and reagents used in the

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method (column 36, lines 10-40). Thus, Anderson et al teach the known technique of circulating a fluid through a microfluidic channel to bring the solution into contact with immobilized probes.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the method comprising FET immobilized probes as taught by Lindsay et al so that the fluid is circulated through a microfluidic channel to bring the solution into contact with immobilized probes as taught by Anderson et al to arrive at the instantly claimed method with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a method having the added advantage of aiding in the mixing of samples and reagents used in the method as explicitly taught by Anderson et al (column 36, lines 10-40). In addition, it would have been obvious to the ordinary artisan that the known technique of using the circulation of a fluid through a microfluidic channel to bring the solution into contact with immobilized probes as taught by Anderson et al could have been applied to the method of Lindsay et al with predictable results because the known technique of circulating a fluid through a microfluidic channel to bring the solution into contact with immobilized probes as taught by Anderson et al predictably results in reliable mixing of reagents used in chip-based assays.

Double Patenting

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The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1 and 19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 17 of copending Application No. 10/501 772. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims differ in that the instant claims specify a reaction buffer with a salt concentration and two measurement points with different interactions. Similarly, the copending application broadly recites an electrolyte solution and measuring two active zones. The instant claims are a species of the copending application. Thus, the conflicting claims are not patentably distinct from each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JERRY LIN whose telephone number is (571)272-2561. The examiner can normally be reached on 7:30-6:00pm, M-TH.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie A. Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jerry Lin/
Primary Examiner, Art Unit 1631
2/15/2010